EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

ANTIMICROBIAL PROGRAM BRANCH

EFFICACY REVIEW - FORM 1

Date EPA Received: 2 October 1995 Date EETMS Received: 25 Oct 1995

Project Return Date: 9 April 1996 Review Start Date: 3 November 95

Review Completion Date: 6 November 1995

Reviewed By: Michele E. Wingfield, Microbiologist

Lan Code:

EPA Reg. No. or File Symbol: 52252-4

EPA Petition or EUP No.: None

Product Type: Sterilant/Disinfectant

MRID No(s): 437232-01 438018-01

Product Manager & Team No.: Marion J. Johnson - 31

Product Name: Minncare Cold Sterilant

Company Name: Minntech Corp.

Submission Purpose: Addendum to June 6, 1995 submission to add a claim for use as a non-porous food contact surface sanitizer.

Product Formulation: Liquid to be diluted prior to use.

ACTIVE INGREDIENT(S)	%
Hydrogen peroxide	22.0
Peroxyacetic Acid	4.5

200.0 **INTRODUCTION**

200.1 **USE(S):**
For the sterilization and disinfection of hard environmental surfaces. Refer to the attached labeling for specific uses.

200.2 **BACKGROUND INFORMATION**
This submission is an addendum to the June 6, 1995 submission to add a sanitization claim for non-porous food contact surfaces. Included with this submission is additional efficacy data to support this claim.

201.0 **DATA SUMMARY**

201.1 **BRIEF DESCRIPTION OF TESTS**

MRID #437232-01
AOAC Germicidal and Detergent Sanitizing Action of Disinfectants: "The Evaluation of the Germicidal Sanitizing Action of Minncare against Staphylococcus aureus and Escherichia coli." Performed at ViroMed Laboratories, Inc., 5500 Feltl Road, Minneapolis, MN 55447. Study completed on March 11, 1993. By: Mary K. Bennett, M.T.

MRID #438018-01
AOAC Germicidal and Detergent Sanitizing Action of Disinfectants: "The Evaluation of the Germicidal Sanitizing Action of Minncare against Staphylococcus aureus." Performed at ViroMed Laboratories, Inc., 5500 Feltl Road, Minneapolis, MN 55447. Study completed on March 5, 1993. By: Mary K. Bennett, M.T.

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

ANTIMICROBIAL PROGRAM BRANCH

EFFICACY REVIEW - FORM 2

EPA Registration: 52252-4

Date EPA Received: 2 October 1995

Date EETMS Received: 25 October 1995

Project Return Date: 9 April 1996

Review Start Date: 3 November 1995

Review Completion Date: 6 November 1995

MRID No(s): 437232-01 438018-01

Product Manager & Team No.: Marion J. Johnson - 31

Product Name: Minncare Cold Sterilant

Company Name: Minntech Corporation

202.0 **RECOMMENDATIONS**

202.1 **EFFICACY SUPPORTED BY THE DATA**

MRID #437232-01 and #438018-01
The submitted efficacy data are acceptable to support the claim for Minncare Cold Sterilant, EPA Reg. No. 52252-4, as a sanitizer on hard, non-porous food contact surfaces, when tested at a dilution of 1:32 (diluted in purified water) against Staphylococcus aureus and Escherichia coli, for a contact time of 30 seconds at 25°C.

203.0 **LABELING**

1. Under the Directions for Use as a Cleaner/Sanitizer (Food Contact Surfaces):

   Instructions must be provided for thoroughly washing the surfaces or objects with a good detergent or compatible cleaner, followed by a potable water rinse prior to application of the sanitizing solution.

   Add the statement "Fresh sanitizing solution should be prepared daily or more often if the solution becomes diluted or soiled."

   Remove the instructions for use at "2 minutes at 57°F (14°C)", efficacy data has not been submitted to support this claim.

2. Add the "Reverse Osmosis Application Note" to the "Directions for Disinfection of RO Membranes".

   Remove the word "disinfect" and replace it with "sanitize" wherever it appears in the "Directions for Disinfection of RO Membranes".

   The "Directions for Disinfection of RO Membranes" must be changed to read: "Directions for **Sanitization** of RO Membranes".

3. The FDA/EPA MOU "disclaimer":

   > "This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean

ordecontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection".

which is now found under PRODUCT EFFICACY on the label must be transferred to appear under "DIRECTIONS FOR STERILIZATION" and under "DIRECTIONS FOR HOSPITAL DISINFECTION".

4. Under the heading "USES" change

"...Primarily intended for sterilization or disinfection of surfaces such as:"... to read:

"...Primarily intended for sterilization, disinfection **or sanitization** of surfaces such as:"